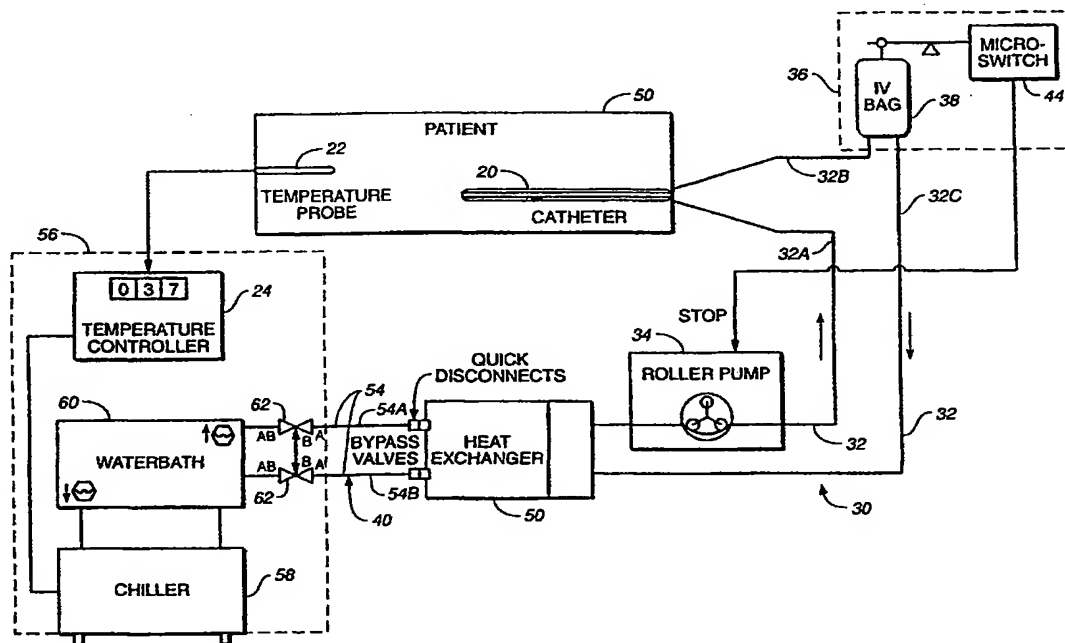




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(54) Title: COOLING SYSTEM FOR INDWELLING HEAT EXCHANGE CATHETER



(57) Abstract

A system for exchanging heat with a body of a patient for cooling or warming the patient, provides for automatic temperature control in accordance with the monitored temperature of the patient. The system includes at least one fluid circuit (30) in communication with the indwelling catheter (20), and a temperature control module (24) wherein in body temperature measurements are used to control the temperature of the fluid circulating within the fluid circuit.

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COOLING SYSTEM FOR INDWELLING HEAT EXCHANGE CATHETER

BACKGROUND OF THE INVENTION

1. Field of the Invention

5 This invention relates generally to methods and apparatus for exchanging heat with the body of a patient.

2. Description of Related Art

Many advantages of hypothermia are well known. By way of example, it has been found particularly desirable to lower the temperature of body tissue in order to reduce the metabolism of the body. In stroke, trauma and several other pathological conditions, hypothermia also reduces the permeability of the blood/brain barrier. It inhibits release of damaging neurotransmitters and also inhibits calcium-mediated effects. It is also known that hypothermia inhibits brain edema and lowers intracranial pressure.

15 Hypothermic treatment has been typically addressed systemically, meaning that the overall temperature of the entire body has been lowered to achieve the advantages noted above. This has been particularly desirable in surgical applications where the reduced metabolism has made it possible to more easily accommodate lengthy operative procedures. An example of this systemic approach includes catheters for transferring heat to or from blood flowing within

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a patient's vessel, as disclosed by Ginsburg in U.S. Patent No. 5,486,208. A closed loop heat exchange catheter is also disclosed by Saab in U.S. Patent No. 5,624,392. A cooling device for whole-body hyperthermia that utilizes the circulatory system of the body is known to be more efficient since the entire
5 volume of the body is constantly perfused with the cold fluid at a capillary level.

Likewise, various other means of cooling the body have been tried with cooling blankets, ice water bladder lavages, ice baths, esophageal catheters and their associated methods. All of these devices require a considerable time to cool the body since the primary heat transfer occurs through the skin or the skull. A
10 more efficient body cooling device that can quickly cool and accurately control the body temperature is required.

BRIEF SUMMARY OF THE INVENTION

The present invention provides a heat exchange system wherein a self-contained primary cooling circuit having a first fluid circulating therein is
15 coupled to a self-contained secondary cooling circuit in a heat exchange relationship. The two circuits are in fluid-flow isolation from each other and are provided with associated pumping mechanisms to effect fluid circulation therein. The primary circuit is in fluid communication with an indwelling heat exchange catheter adapted for insertion into the body of the patient in order to effect heat
20 exchange with a target site in the body. The secondary circuit is cooled or warmed by a temperature control system.

In one aspect of the present invention, the temperature of the system is controlled in accordance with patient temperature determinations. This can be

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performed automatically, in a closed feedback loop wherein temperature readings from a probe are input to a temperature controller having inputs to at least one of the pumping mechanisms in addition to the heater or cooler of the temperature control system. The temperature controller operates in accordance with

5 temperature control algorithms taking into account the various system and patient parameters to thereby achieve and maintain desired temperature conditions in the patient's body.

BRIEF DESCRIPTION OF THE DRAWINGS

Many advantages of the present invention will be apparent to those skilled in the art with a reading of this specification in conjunction with the attached drawings, wherein like reference numerals are applied to like elements and
5 wherein:

FIG. 1 is a schematic diagram of a temperature control system in accordance with the invention;

FIGS. 2 and 3 are schematic diagrams of a fluid level detector in an untriggered and a triggered state, respectively, in accordance with one aspect of
10 the invention;

FIG. 4 is a schematic partial cross-sectional side elevational view of a fluid level detection system in accordance with a second aspect of the invention, wherein the volume reservoir is in the inflated configuration;

FIG. 5 is a schematic partial cross-sectional top view of the detection
15 system of FIG. 4;

FIG. 6 is a schematic partial cross-sectional side elevational view of the detection system of FIG. 4, wherein the volume reservoir is in the deflated configuration;

FIG. 7 is a schematic partial cross-sectional top view of the detection
20 system of FIG. 6; and

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FIG. 8 is a schematic diagram showing the heat exchange control in accordance with the invention.

DETAILED DESCRIPTION OF THE INVENTION

A heat exchange catheter and method of operation are disclosed in co-
5 pending U.S. patent application Serial No. 09/063,984, entitled "Indwelling Heat
Exchange Catheter and Method of Using Same," incorporated herein by
reference in its entirety. The system of the aforementioned application is adapted
to produce hypothermia or hyperthermia, typically in a selected portion of the
body without substantially varying the temperature of the remaining portions of
10 the body. The selected body portion will usually be associated with a body
conduit which conveys a body fluid to the selected body portion. Of particular
interest are the organs of the body which are commonly nourished and
maintained by a flow of blood in the arterial system. For example, a flow of
blood is introduced to the brain through the carotid artery. Of course the
15 temperature of this blood is usually at the normal body temperature.

By positioning an indwelling heat exchange catheter in the body conduit,
heat can be added to or removed from the body fluid to heat or cool the selected
body portion. For example, the heat exchange catheter can be disposed in the
carotid artery where the arterial blood flowing to the brain can be cooled. The
20 flow of cooled blood to the brain reduces the temperature of the brain, thereby
resulting in cerebral hypothermia. This temperature reduction can be confined to
the brain or other body portion, while the remaining portions of the body
maintain a generally normal body temperature. In accordance with this method,
the selected body portion can be cooled to thereby provide the advantages
25 associated with hypothermia for that body portion. The remainder of the body,

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such as the portions other than the brain, do not necessarily experience the reduction in temperature. Of course, selective cooling is application dependent and it should be recognized that in some situations selective cooling may give way to systemic cooling in which the temperature of the whole body of the
5 patient is cooled using a similar approach.

Several factors are of interest in effecting heat transfer in a heat exchanger. These factors include, for example, the convection heat transfer coefficient of the two fluids involved in the heat exchange, as well as the thermal conductivity and thickness of the barrier between the two fluids. Other factors
10 include the relative temperature differential between the fluids, as well as the contact area and residence time of the heat transfer. The Reynolds number for each fluid stream affects boundary layers, turbulence and laminar flow.

In the system of the aforementioned patent application a catheter is provided with an elongated configuration, a proximal end and a distal end, and
15 an inner tube having a second lumen disposed within the first lumen of an outer tube. Portions of the inner tube define a first flow path extending along the second lumen, while portions of the tubes define a second flow path extending between the first tube and the second tube. In one embodiment, a plurality of hollow fibers provide fluid communication between the first and second flow
20 paths, and a heat exchange fluid is disposed in the hollow fibers to cool the fibers.

The fluid circulated in the heat exchanger catheter of the above-described system is preferably biocompatible in order to reduce the chance of harm to the patient should inadvertent rupture and fluid leakage into the patient's body occur.
25 Additionally, it is clear that the sterility of the fluid and tubing set needs to be

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maintained. Known prior art devices fall short of the high sterility standard because of their use of a single circuit to deliver cooling fluid to the patient. Specifically, in systems such as those disclosed U.S. Patents nos. 3,460,538 (Armstrong), 4,298,006 (Parks), 5,437,673 (Bauset, et al.) and 5,624,392 (Saab), a heat exchange means adapted for insertion into a body cavity is connected in fluid communication directly to the cooling/heating source and other support devices. This arrangement is susceptible to contamination, and it becomes necessary to maintain sterility of all the support devices if the heat exchange means is intended to be used in particularly sensitive regions such as the bloodstream of the patient. This difficult sterility standard is not problematic in for example the Armstrong patent which is limited to use in body cavities such as the intestines as accessed through the mouth or stomach, or in the Baust, et al. patent intended for insertion into the urethra. On the other hand, in the patents of Saab and Parks, where direct contact with patient blood is contemplated, severe limitations are encountered in that all the equipment must be sterile, imposing great expense in equipment and manpower.

Notwithstanding the need for localized hypothermia, there will always be those procedures which call for systemic hypothermia. Many of the advantages associated with the present invention will greatly facilitate those procedures, for example by decreasing the number and complexity of operative steps, increasing the heat transfer capacity of the device, and addressing other concerns such as the formation of blood clots.

FIG. 1 diagrammatically shows a system in which a temperature control unit is shown in thermal communication with an indwelling catheter via primary and secondary fluid circuits connected in sequence. The temperature control unit and the secondary fluid circuit are self-contained and interface with the primary

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fluid circuit via a heat exchanger. The indwelling catheter is disposed in the body of the patient and serves to remove heat from or provide heat to at least a portion of the patient's body, although as discussed above the entire body temperature of the patient can thus be selectively altered, as is the preferred application of the present invention. The indwelling catheter is in fluid communication with a sterile tubing set having a heat exchange fluid circulating therein, with the tubing set, indwelling catheter and heat exchange fluid forming the primary fluid circuit. The temperature control module may provide automatically controlled heating or cooling in accordance with temperature measurements of the body of the patient, using a closed feedback loop, to thereby automatically achieve and maintain target temperature conditions.

As shown in FIG. 1, an indwelling catheter 20 of the type adapted for insertion into the body of the patient 50 in a particular body cavity and is preferably any one of the type of indwelling catheters disclosed in co-pending U.S. patent application Serial No. 09/063,984 mentioned above and herein incorporated by reference in its entirety. As shown, catheter 20 is in fluid communication with a sterile tubing set 32. Catheter 20 and tubing set 32 form part of a primary fluid circuit 30 through which a first fluid is circulated in order to warm or cool a target site in the body in thermal communication with the catheter 20. It will be appreciated that the target site, such as the brain of the patient 50, may be in direct contact with the inserted catheter 20, or it may be in thermal communication with the catheter via a fluid or tissue channel such that heat transfer between the target site and the catheter 20 occurs through the fluid or tissue. For example, it is contemplated that the catheter 20 be implanted antegrade in the blood supply to the brain, with the blood, cooled by the catheter, serving to alter the temperature of the brain and blood to thereby achieve the desired benefits of hypothermia such as reducing the permeability of the

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blood/brain barrier, inhibiting the release of neurotransmitters, inhibiting calcium-mediated effects, inhibiting brain edema and lowering intracranial pressure. Additionally, although discussed in terms of brain surgery, it will be appreciated that the invention can be practiced in connection with surgery to different portions of a patient's body, such as for example heart bypass surgery, in which extracorporeal procedures are involved. Specifically, use of the remote control feature of the system of the invention would eliminate the requirement of constant human intervention and management of the heater/cooler to adjust temperature. A feedback loop from the heat exchanger blood outlet, or alternatively from a patient site, to the temperature controller would enable the system to self regulate the water supply to the heat exchanger at an appropriate temperature to achieve the target temperature that is entered by the operator. This strategy could be used to regulate patient temperature at a constant value or to control cooling and reheating. Preprogrammed temperature profiles can be used to control rate of change optimized for therapeutic benefit. In this manner, temperature control can be effected in procedures which involve circulation of blood outside of the body that often employ the use of heat exchangers to control the temperature of the blood thus effecting the temperature of the patient. Such procedures include ECMO (long term extracorporeal membrane oxygenation) and heart lung (cardiopulmonary) bypass surgery, which are typical examples where a heat exchanger is used not only to offset the effects of the blood circulating in tubing at room temperature but also to institute hypothermia for clinical purposes.

Pump 34 may be of conventional design, but preferably is a roller pump in order to maintain the integrity of the self-contained primary circuit and thereby preserve its sterility. Other types of pumps which may be used are diaphragm pumps, bladder pumps, piston pumps, peristaltic pumps, etc., all of which are

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known in the art. Pump 34 serves to circulate the first fluid through the tubing set 32 and catheter 20. Pump 34 is preferably coupled to segment 32A of primary circuit 30, although other segments can be used for this purpose. The first fluid is preferably biocompatible and is thus selected in order to minimize the harm to the patient in case of inadvertent leakage into the patient's body. Sterile water or saline are two candidate solutions, although other fluids may be used. Considerations other than biocompatibility which are to be taken into account in selecting an appropriate solution are heat transfer properties, viscosity, freezing point and compatibility with materials used, among other factors.

To detect fluid leakage in primary circuit 30, an arrangement in accordance with the invention utilizes a fluid level detection system 36 comprising a fluid volume reservoir, which is preferably a conventional IV (intravenous) bag (38), supported in a frame 42 in the manner shown in FIGS. 2 and 3. Intravenous bag 38 mates with segments 32B and 32C of tubing set 32 using conventional fittings 48 and 52. A switch 44 having a movable lever 46 normally biased outward in the direction of intravenous bag 38 is disposed against the intravenous bag 38 such that when the bag is at an acceptably filled level, the bag is inflated and the weight and/or pressure in the bag urges the movable lever 46 to a first position corresponding to a first state of the switch 44, while when the bag is at an unacceptably depleted level, due to fluid loss from the primary circuit 30, the bag deflates and the movable lever 46, urged by for example a spring mechanism (not shown), returns to the normal, outward-biased position which corresponds to a second state of the switch 44. At the second state switch 44 may be used to actuate pump shutoff or other corrective action, such as providing an audible or visible alarm to the operator. It will be appreciated that switch 44 can be triggered using other schemes, such as those relying on the weight of a suspended IV bag or reservoir for example, or other,

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known level detection devices of the optical or capacitive type, can be used in the invention without departure from the spirit and scope thereof.

FIGS. 4-7 show a second arrangement of a fluid level detection system in accordance with the invention. Frame 64 comprises a support plate 66 and a mounting pole 68 having a hook 70 at the top thereof. Mounting pole 68 and hook 70 operate to suspend a fluid volume reservoir such as IV bag 38 in the frame 64. A switch assembly 74 is mounted in a capture arm 76 which is pivotably mounted such that when the capture arm 76 is in the engaged position shown, switch lever 78 of microswitch 80 protrudes inwardly towards IV bag 38. When the bag is inflated with fluid (FIGS. 4 and 5), switch lever 78 is effectively depressed such that microswitch 80 is in a first state, while when the bag is deflated due to loss of fluid (FIGS. 6 and 7), switch lever 78, normally urged away from microswitch 80 by a biasing means such as a spring (not shown) protrudes outwards and disposes microswitch 80 in a second state. These two states can be distinguished to provide an indication of fluid level in primary fluid circuit 30 with which IV bag 38 is in fluid communication via IV spike 82 for example.

In addition to serving as a volume gain or loss detector, fluid detection system 36 provides several advantages enhancing the safe practice of the present invention. For example, the volume reservoir (IV bag 38) serves as an air trap to remove deleterious pockets of air from the primary fluid circuit 30 and as a source of priming volume to the primary fluid circuit. Additionally, the volume reservoir provides a fluid volume buffer to accommodate modulations in the primary fluid circuit 30.

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Primary circuit 30 is in heat exchange relationship with a secondary circuit 40 containing a second fluid circulating therein. A sterile heat exchanger 50 is provided for this purpose and forms part of the sterile primary circuit 30. Heat exchanger 50 interfaces between the two fluid circuits and serves to
5 facilitate heat transfer therebetween in a well known manner whose details will be omitted herein for purposes of clarity. Like tubing set 32, heat exchanger 50 of primary circuit 30 is sterile and is preferably disposable and may be integrally formed with or removably coupled to the tubing set 32. The nature of fluid
10 pump 34 is such that the tubing set 32, along with heat exchanger 50 in the integrally-formed configuration, can be readily removed and replaced with each new patient use.

Fluid circuits 30 and 40 retain their fluids in isolation from each other in order to maintain the sterility of at least primary fluid circuit 30 and to permit the use of a non-biocompatible fluid in secondary fluid circuit 40. Advantages of
15 non-biocompatible fluids, such as for example an anti-freeze/water mixture, include the ability to achieve temperatures below the 0°-Celcius limit imposed by water or saline, and thereby provide for a more rapid cooling down process especially at initial system start-up when component and fluid temperatures have to be rapidly lowered from their room temperature state.

20 Secondary circuit 40 comprises tubing set 54 having segments 54A and 54B which are preferably removably coupled to heat exchanger 50. A temperature control module 56 serves to cool or warm the second fluid circulating in tubing set 54 in a controlled manner to be described below. Temperature control module 56 is provided with a chiller 58 and a heater (not
25 shown) which operate to controllably alter the temperature of the second fluid, either directly or via a waterbath 60 in a well known manner. Use of a heat

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source is preferred in order to provide for more precise control of the temperature of the second fluid, and to permit the use of the system to warm the temperature of a target site in the body of the patient, especially after a preceding cooling phase. A pump 26 (FIG. 8) circulates the second fluid through the secondary fluid circuit 40, thereby retaining the secondary circuit at the desired temperature. Because during initial startup it may be desirable to accelerate the cooling process, the efficiency of the system can be increased by provision of bypass valves 62 which at startup are utilized to restrict fluid circulation in secondary circuit 40 primarily to the fluid within module 56.

To provide temperature control especially during systemic cooling or heating in which it is desired to cool or warm the entire body of the patient, the patient's body temperature is measured and temperature control module 56 is operated accordingly. This may be effected manually by the operator, or automatically, using one or more temperature probes 22 (only one is shown) inserted into the body of the patient 50, rectally for example. Clearly, in the systemic heat exchange application, the temperature probes 22 need not be positioned in proximity with the site at which the indwelling catheter 20 is disposed, but rather can be placed anywhere from which a core body temperature measurement can be attained. In the automatic arrangement shown schematically in FIG. 1, the temperature measurement from probe 22 is provided as feedback in a closed loop to a proportional temperature controller 24. Any suitable processing device can operate as the proportional temperature controller 24 and serves to control the temperature of the second fluid by controlling the amount of cooling or heating to which the second fluid of secondary circuit 40 is subjected. Proportional temperature controller 24 can also be used to adjust the circulation rates in the primary and/or secondary circuits in accordance with the temperature measurement signals from probe 22. Such adjustment can be effected using

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direct control of the pumping rates of pumps 26 and 34 as shown in FIG. 8. Proportional temperature controller 24 is programmed with appropriate time constants based on the location of probe 22 in the patient's body and the corresponding temperature response time of the system and the body. As

5 mentioned above, probe 22 can be placed anywhere in the body and is not necessarily restricted to proximity to the target site, as long as the correlation between the temperature at the actual probe location and that at the target site is known. One example of such a correlation is the knowledge that arterial blood

10 temperature will ultimately determine brain temperature, and the relationship between these two can be used to program the temperature control algorithm employed by the proportional temperature controller 24 to achieve a target temperature or temperature range in the brain. Similarly, a plurality of probes

15 22 can be used to provide feedback to proportional temperature controller 24, with some or even all of these probes being placed exteriorly of the body at various locations in the system--for example, at the primary and/or secondary

20 circuits 30 and 40. Control over such an arrangement can be effected if the relationship of the various fluid circuits and components of the system can be properly correlated to that of the patient 50, with parameters such as patient weight, height, temperature, circulatory rate, etc. being taken into account to ensure safe and proper operation.

As mentioned above, the invention can be practiced in connection with surgery to various parts of the body and is not restricted to surgery to the brain. For example, the system of the invention can be used to provide auto feedback and temperature control during heart bypass surgery, or during other types of

25 surgery as one of ordinary skill in the art will appreciate.

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In accordance with the invention, the feedback scheme of the invention can be used to maintain desired temperature conditions for a patient. Specifically, the system can be used to control any temperature deviations from an acceptable temperature range, which may be a normothermic range, whereby
5 probes 22 will trigger cooling or heating of the patient's body depending on this sensed deviation. Moreover, since this deviation is generally indicative of certain physiological activity of which the physician should be apprised, the operation of the system can be used as an indication that this physiological activity is taking place. For instance, when the cooling operation of temperature control module
10 56 is triggered due to a rise in the patient's core body temperature, the system cooling activity, as reflected in the increased workload of the cooling componentry of the system, is then used to indicate to the physician, audibly or visibly using an alarm or other status indicator device (not shown), that the patient's body is attempting to enter a fever state. Appropriate measures can then
15 be taken. Of course, parameters other than workload can be used to provide this indication, such as the slope of the temperature feedback along with the sign of the slope.

The above are exemplary modes of carrying out the invention and are not intended to be limiting. It will be apparent to one of ordinary skill in the art that
20 modifications thereto can be made without inventive departure from the spirit and scope of the invention as set forth in the following claims.

CLAIMS

1. An apparatus for changing and maintaining the temperature of at least a portion of the body of a patient, the apparatus comprising:

an indwelling catheter adapted for heat exchange within the body;

5 a primary fluid circuit in fluid flow communication with the indwelling catheter, the primary circuit adapted to contain a first circulating fluid therein;

a secondary fluid circuit which is in heat exchange relationship with the primary fluid circuit and adapted to contain a second circulating fluid therein, the first and second fluids being in fluid-flow isolation from each other; and

10 a temperature control module for changing the temperature of the second fluid.

2. The apparatus of Claim 1, wherein the temperature control module is adapted to automatically heat or cool the second fluid in accordance with a sensed temperature of the body of the patient such that a desired body
15 temperature is approached.

3. The apparatus of Claim 2, further comprising a temperature probe for providing a body temperature signal representative of the body temperature of the patient, the temperature control module having a temperature controller for receiving the body temperature signal and actuating heating or cooling of the
20 second fluid in accordance with a temperature control algorithm.

4. The apparatus of Claim 2, further comprising:
a first pump for effecting circulation of the first fluid in the primary fluid circuit at a first rate;

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a second pump for effecting circulation of the second fluid in the secondary fluid circuit at a second rate; and

a temperature controller for automatically controlling at least one of the heating, cooling, first rate and second rate in accordance with a sensed
5 temperature of the body of the patient.

5. The apparatus of Claim 1, further comprising a heat exchanger for effecting heat exchange between the primary and secondary fluid circuits.

6. The apparatus of Claim 4, wherein the first pump is a roller pump.

7. The apparatus of Claim 1, wherein the primary circuit is provided
10 with a detector for sensing fluid loss.

8. The apparatus of Claim 7, wherein the detector for sensing fluid loss comprises:

a fluid volume reservoir in fluid communication with the primary circuit, the fluid volume reservoir assuming a first configuration when the first fluid level
15 is at an acceptable level and assuming a second configuration when the first fluid level is at an unacceptable level;

a switch adapted to toggle between first and second states depending on the configuration of the fluid volume reservoir.

9. The apparatus of Claim 8, wherein the switch initiates corrective
20 action when at one of the first and second states.

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10. The apparatus of Claim 9, wherein the fluid volume reservoir is in an inflated configuration when the first fluid level is at an acceptable level and is in a deflated configuration when the first fluid level is at an unacceptable level, and wherein the switch is provided with a movable actuating lever biased against the fluid volume reservoir such that the lever causes the switch to toggle between the first and second states depending on the configuration of the fluid volume reservoir.

11. The apparatus of Claim 1, further comprising a status indicator for providing an indication of the operation of the temperature control module.

10 12. A system for changing the body temperature of a patient, the system comprising:

an indwelling catheter adapted for heat exchange with the body of the patient;

15 a primary fluid circuit in fluid communication with the indwelling catheter, the primary fluid circuit adapted to contain a first circulating fluid therein;

a temperature control module for automatically changing the temperature of the first fluid in accordance with a sensed temperature of the body of the patient such that a desired body temperature is approached.

20 13. The system of Claim 12, further comprising a temperature probe for providing a body temperature signal representative of the body temperature of the patient, the temperature control module actuating heating or cooling of the first fluid in accordance with a temperature control algorithm.

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14. The system of Claim 13, further comprising:
a first pump for effecting circulation of the first fluid in the primary fluid
circuit at a first rate; and
a temperature controller for controlling at least one of the heating,
5 cooling, and first rate in accordance with a sensed temperature of the body of the
patient.

15. The system of Claim 12, further comprising a secondary fluid
circuit in heat exchange relationship with the primary fluid circuit and adapted to
contain a second circulating fluid therein, the first and second fluids being in
10 isolation from each other.

16. The system of Claim 15, further comprising a heat exchanger for
effecting heat exchange between the primary and secondary fluid circuits.

17. The system of Claim 1, wherein the first pump is a roller pump.

18. The system of Claim 12, wherein the primary circuit is provided
15 with a detector for sensing fluid loss.

19. The system of Claim 18, wherein the detector for sensing fluid
loss comprises:

a fluid volume reservoir in fluid communication with the primary circuit,
the fluid volume reservoir assuming a first configuration when the first fluid level
20 is at an acceptable level and assuming a second configuration when the first fluid
level is at an unacceptable level;

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a switch adapted to toggle between first and second states depending on the configuration of the fluid volume reservoir.

20. The system of Claim 19, wherein the switch initiates corrective action when at one of the first and second states.

5 21. The system of Claim 20, wherein the fluid volume reservoir is in an inflated configuration when the first fluid level is at an acceptable level and is in a deflated configuration when the first fluid level is at an unacceptable level, and wherein the switch is provided with a movable actuating lever biased against the fluid volume reservoir such that the lever causes the switch to toggle between
10 the first and second states depending on the configuration of the fluid volume reservoir.

22. The system of Claim 12, further comprising a status indicator for providing an indication of the operation of the temperature control module.

15 23. An apparatus for changing or maintaining the temperature of at least a portion of a body of a patient, the apparatus comprising:
 means for exchanging heat with the portion of the body;
 a primary fluid circuit in fluid communication with the means for exchanging heat, the primary circuit adapted to contain a first circulating fluid therein;

20 a secondary fluid circuit in heat exchange relationship with the primary fluid circuit and adapted to contain a second circulating fluid therein, the first and second fluids being in isolation from each other; and
 means for changing the temperature of the second fluid.

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24. The apparatus of Claim 23, wherein the means for changing the temperature comprises a temperature control module adapted to automatically heat or cool the second fluid in accordance with a sensed temperature of the body of the patient such that a desired body temperature is approached.

5 25. The apparatus of Claim 24, further comprising a temperature probe for providing a body temperature signal representative of the body temperature of the patient, the temperature control module adapted to receive the body temperature signal and actuate heating or cooling of the second fluid in accordance with a temperature control algorithm.

10 26. The apparatus of Claim 25, further comprising:
a first pump for effecting circulation of the first fluid in the primary fluid circuit at a first rate;
a second pump for effecting circulation of the second fluid in the secondary fluid circuit at a second rate; and
15 a temperature controller for automatically controlling at least one of the heating, cooling, first rate and second rate in accordance with the sensed temperature of the body of the patient.

27. The apparatus of Claim 23, further comprising a heat exchanger for effecting heat exchange between the primary and secondary fluid circuits.

20 28. The apparatus of Claim 26, wherein the first pump is a roller pump.

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29. The apparatus of Claim 23, wherein the primary circuit is provided with a detector for sensing fluid loss.

30. The apparatus of Claim 29, wherein the detector for sensing fluid loss comprises:

5 a fluid volume reservoir in fluid communication with the primary circuit, the fluid volume reservoir assuming a first configuration when the first fluid level is at an acceptable level and assuming a second configuration when the first fluid level is at an unacceptable level;

10 a switch adapted to toggle between first and second states depending on the configuration of the fluid volume reservoir.

31. The apparatus of Claim 30, wherein the switch initiates corrective action when at one of the first and second states.

32. The apparatus of Claim 31, wherein the fluid volume reservoir is in an inflated configuration when the first fluid level is at an acceptable level and
15 is in a deflated configuration when the first fluid level is at an unacceptable level, and wherein the switch is provided with a movable actuating lever biased against the fluid volume reservoir such that the lever causes the switch to toggle between the first and second states depending on the configuration of the fluid volume reservoir.

20 33. The apparatus of Claim 23, further comprising a status indicator for providing an indication of the operation of the apparatus.

34. A system for changing the body temperature of a patient, the system comprising:

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means for exchanging heat with the body of the patient;

a primary fluid circuit in fluid communication with the means for exchanging heat, the primary circuit adapted to contain a first circulating fluid therein;

- 5 means for automatically changing the temperature of the first fluid in accordance with a sensed temperature of the body of the patient such that a desired body temperature is approached.

35. The system of Claim 34, further comprising a temperature probe for providing a body temperature signal representative of the body temperature of the patient, the means for automatically changing the temperature of the first fluid adapted to receive the body temperature signal and actuate heating or cooling of the first fluid in accordance with a temperature control algorithm.

36. The system of Claim 35, further comprising:
a first pump for effecting circulation of the first fluid in the primary fluid circuit at a first rate; and
15 a temperature controller for controlling at least one of the heating, cooling, and first rate in accordance with the sensed temperature of the body of the patient.

37. The system of Claim 34, further comprising a secondary fluid circuit in heat exchange relationship with the primary fluid circuit and adapted to contain a second circulating fluid therein, the first and second fluids being in isolation from each other.

38. The system of Claim 37, further comprising a heat exchanger for effecting heat exchange between the primary and secondary fluid circuits.

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39. The system of Claim 36, wherein the first pump is a roller pump.

40. The system of Claim 34, wherein the primary circuit is provided with a detector for sensing fluid loss.

41. The system of Claim 40, wherein the detector for sensing fluid
5 loss comprises:

a fluid volume reservoir in fluid communication with the primary circuit,
the fluid volume reservoir assuming a first configuration when the first fluid level
is at an acceptable level and assuming a second configuration when the first fluid
level is at an unacceptable level;

10 a switch adapted to toggle between first and second states depending on
the configuration of the fluid volume reservoir.

42. The system of Claim 41, wherein the switch initiates corrective
action when at one of the first and second states.

43. The system of Claim 42, wherein the fluid volume reservoir is in
15 an inflated configuration when the first fluid level is at an acceptable level and is
in a deflated configuration when the first fluid level is at an unacceptable level,
and wherein the switch is provided with a movable actuating lever biased against
the fluid volume reservoir such that the lever causes the switch to toggle between
the first and second states depending on the configuration of the fluid volume
20 reservoir.

44. The system of Claim 34, further comprising a status indicator for
providing an indication of the operation of the apparatus.

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45. A tubing set for delivery of a heat exchange fluid between a heat exchanger and an indwelling catheter, the tubing set comprising:

first tubing means for delivery of fluid between the heat exchanger and the indwelling catheter;

5 a second tubing means for delivery of fluid between the indwelling catheter and a fluid reservoir; and

third tubing means for delivery of fluid between the reservoir and the heat exchanger.

46. A detector for sensing fluid level in a fluid circuit comprising:

10 a frame for retaining a fluid volume reservoir in fluid communication with the fluid circuit, the fluid volume reservoir assuming a first configuration when the first fluid level is at an acceptable level and assuming a second configuration when the first fluid level is at an unacceptable level;

15 a switch adapted to toggle between first and second states depending on the configuration of the fluid volume reservoir,

wherein the fluid volume reservoir is in an inflated configuration when the first fluid level is at the acceptable level and is in a deflated configuration when the first fluid level is at an unacceptable level, and wherein the switch is provided with a movable actuating lever biased against the fluid volume reservoir
20 such that the lever causes the switch to toggle between the first and second states depending on the configuration of the fluid volume reservoir.

47. The detector of Claim 46, wherein the fluid volume reservoir is adapted for suspension in the frame.

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48. The detector of Claim 46, the frame further comprising a capture arm on which the switch is mounted.

49. A system for changing the body temperature of a patient, the system comprising:

5 an indwelling catheter adapted for heat exchange with the body of the patient;

a primary fluid circuit in fluid communication with the indwelling catheter, the primary fluid circuit adapted to contain a first fluid therein;

means for circulating the first fluid in the primary fluid circuit;

10 and

means for sensing fluid loss from the primary fluid circuit.

50. The system of Claim 49, wherein the means for sensing comprises:

15 a fluid volume reservoir in fluid communication with the primary fluid circuit, the fluid volume reservoir assuming a first configuration when the first fluid level is at an acceptable level and assuming a second configuration when the first fluid level is at an unacceptable level;

a switch adapted to toggle between first and second states depending on the configuration of the fluid volume reservoir,

20 wherein the fluid volume reservoir is in an inflated configuration when the first fluid level is at the acceptable level and is in a deflated configuration when the first fluid level is at an unacceptable level, and wherein the switch is provided with a movable actuating lever biased against the fluid volume reservoir such that the lever causes the switch to toggle between the first and second states depending on the configuration of the fluid volume reservoir.

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51. The system of Claim 50, further comprising a frame, the fluid volume reservoir being adapted for suspension in the frame.

52. The system of Claim 51, the frame further comprising a capture arm for retaining the fluid volume reservoir therein, the switch being mounted on
5 the capture arm.

53. The system of Claim 49, wherein the means for circulating comprises a roller pump.

54. An apparatus for changing the temperature of at least a portion of the body of a patient, the apparatus comprising:
10 an indwelling catheter adapted for heat exchange within the body;
a primary fluid circuit in fluid flow communication with the indwelling catheter, the primary fluid circuit adapted to contain a first fluid circulating at a first rate therein;
a secondary fluid circuit which is in heat exchange relationship
15 with the primary fluid circuit and adapted to contain a second fluid circulating at a second rate therein, the first and second fluids being in fluid flow isolation from each other; and
a temperature control module for establishing a heat exchange rate between the indwelling catheter and the body of the patient.

20 55. The apparatus of Claim 54, further comprising a temperature probe for providing a body temperature signal representative of the body temperature of the patient, the temperature control module automatically heating or cooling the second fluid in accordance with the body temperature signal.

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56. The apparatus of Claim 54, further comprising a temperature probe for providing a body temperature signal representative of the body temperature of the patient, the temperature control module automatically changing the first rate in accordance with the body temperature signal.

5 57. The apparatus of Claim 54, further comprising a temperature probe for providing a body temperature signal representative of the body temperature of the patient, the temperature control module automatically changing the second rate in accordance with the body temperature signal.

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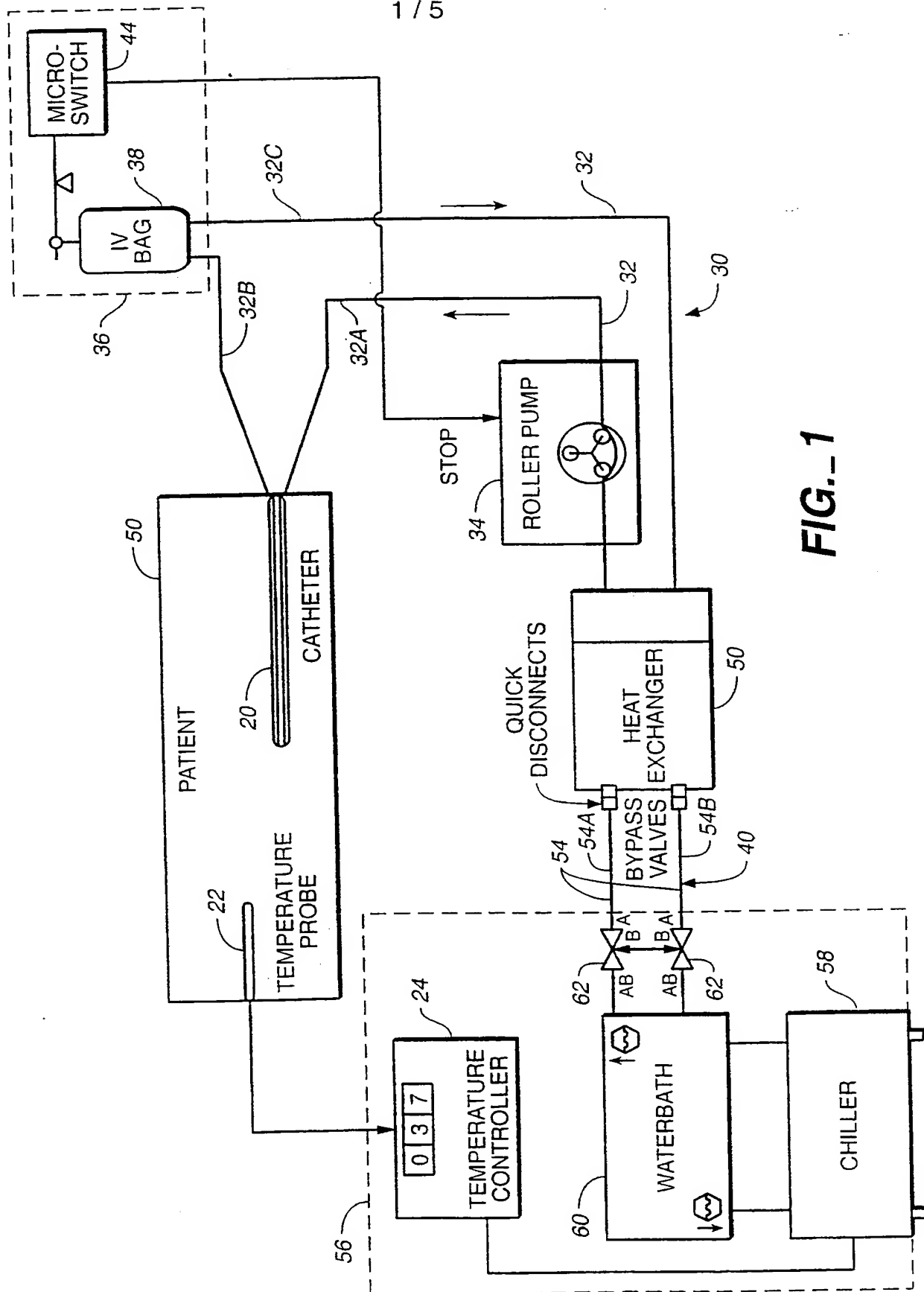
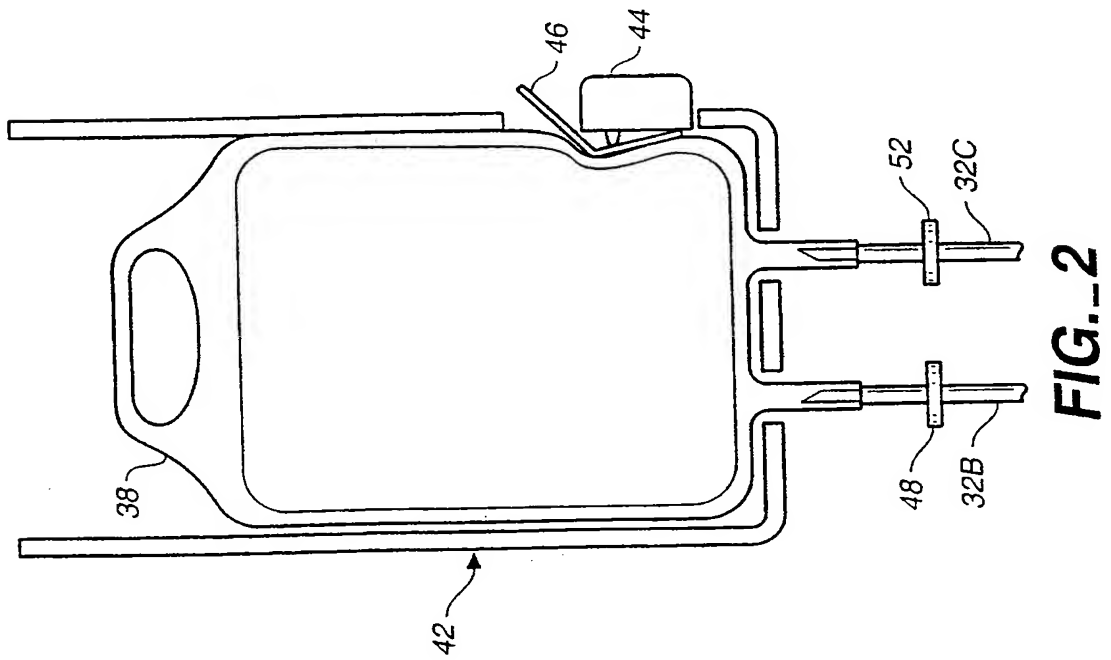
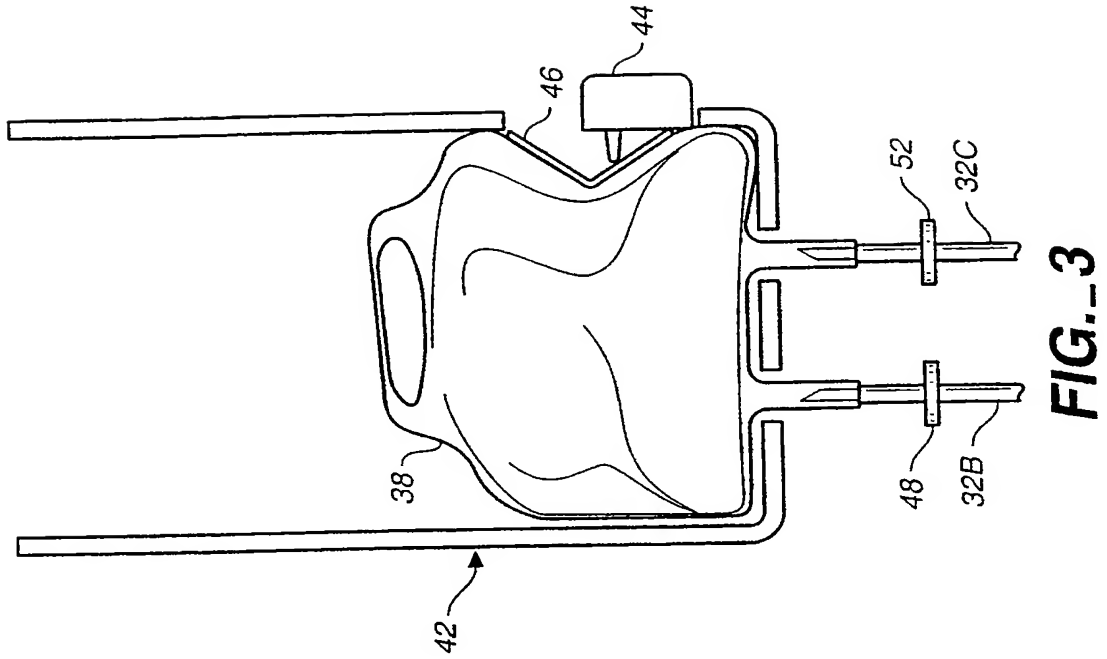
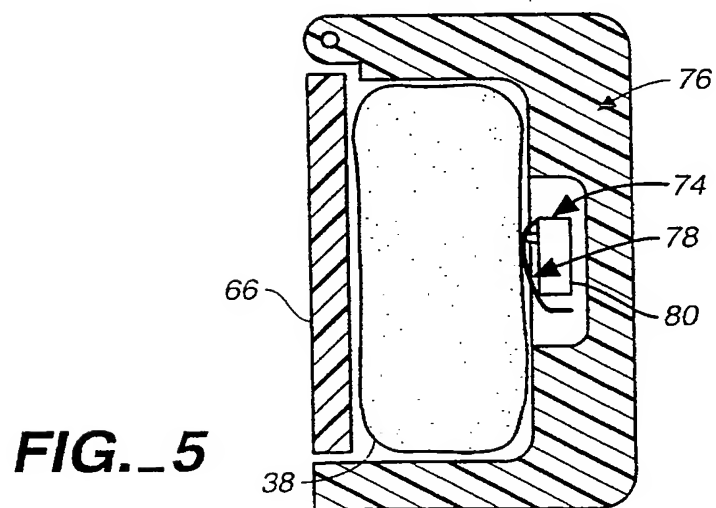
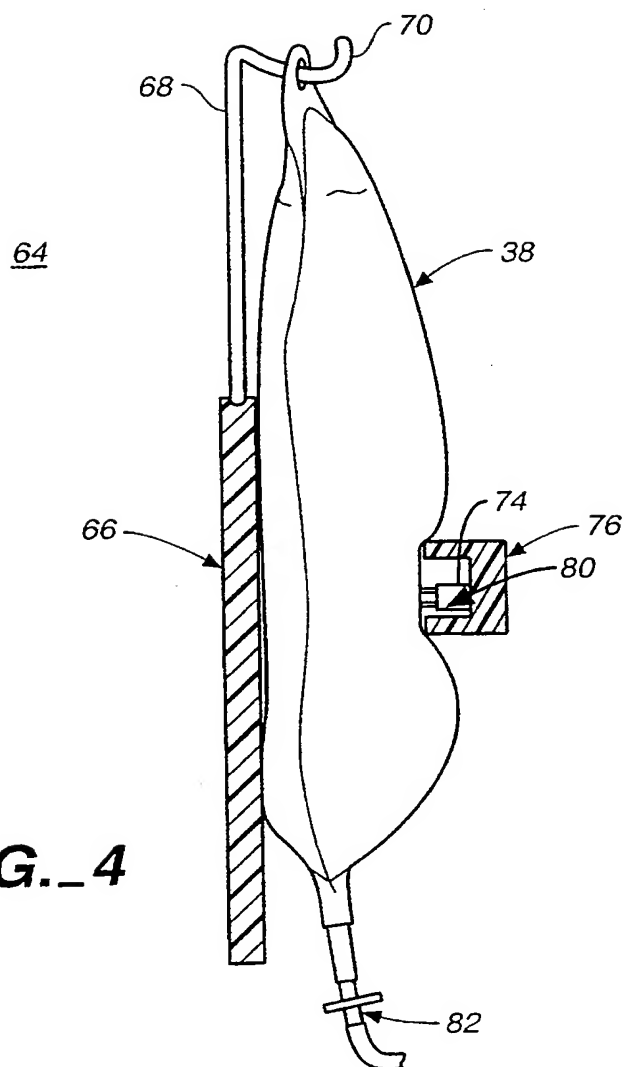


FIG. 1

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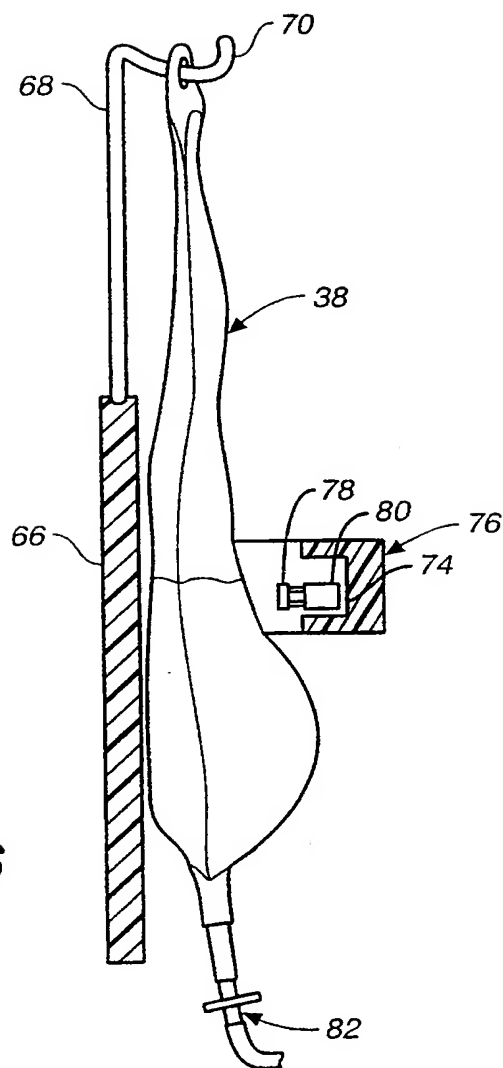


FIG._6

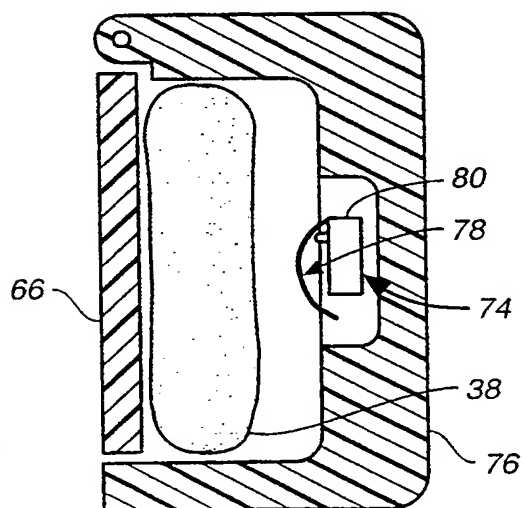


FIG._7

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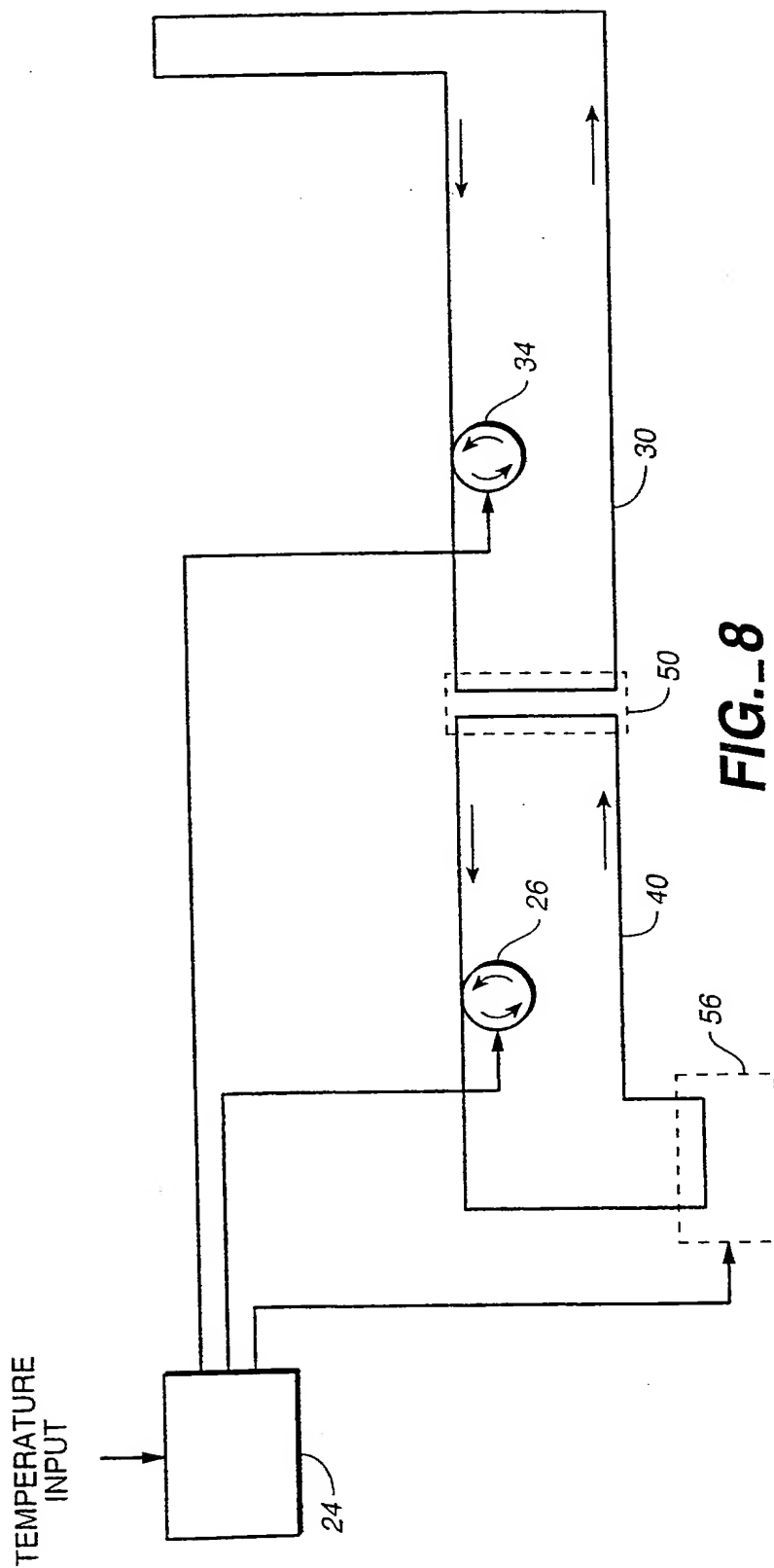


FIG. 8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/31008

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61F 7/00

US CL :607/96, 104, 105, 113

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 607/96, 104, 105, 113

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,733,319 A (NEILSON et al.) 31 March 1998, entire document.	1-3, 12, 13, 24, 25, 35, 54-57 ----- 4-6, 11, 14-17, 22, 26-28, 36-39, 44
Y	US 3,504,674 A (SWENSON et al.) 07 April 1970, entire document.	4-6, 14-17, 26-18, 36-39
Y	US 5,545,137 A (RUDIE et al.) 13 August 1996, entire document.	11, 22, 44
X,P	US 5,879,316 A (SAFAR et al.) 09 March 1999, entire document.	45

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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Date of the actual completion of the international search

24 MARCH 2000

Date of mailing of the international search report

26 APR 2000

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/31008

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,609,591 A (DAIKUZONO) 11 March 1997, entire document.	12-14, 34-36
A	US 3,125,096 A (ANTILES et al.) 17 March 1964, entire document.	1-57

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